

ALPBACH COMMUNIQUÉ: STRENGTHENING EUROPE’S ANTIBIOTIC INDEPENDENCE

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Antibiotics rank among the most important discoveries of human history. They not only significantly increased the average life expectancy and reduced infectious disease mortality but form the prerequisite on which modern medical procedures are founded. Guarding their security of supply is of paramount importance for the operation of our entire healthcare infrastructure in Europe, and in Africa, where falsified antibiotics pose a major threat to Public Health.

BACKGROUND

The production of antibiotics can be divided into two key steps: The manufacture of Active Pharmaceutical Ingredients (APIs) and their formulation into Finished Dosage Forms (FDFs). While the production of FDFs is today globally diversified, the upstream manufacturing of API is highly concentrated—with almost all suppliers located in China. This imbalance creates a strategic cluster risk for Europe in the form of critical dependencies of pharmaceutical supply chains in one of the most fundamental sectors of healthcare systems. This is why European sovereignty in the antibiotics sector is not just a health policy issue, but a question of competitiveness, supply security and, ultimately, a geopolitical question of security.

Furthermore, the few remaining producers of antibiotic API within the EU are struggling to uphold their operations in an environment of unsustainably low market prices, distorted competitive frameworks and heavily subsidised competitors. Antibiotic API production for them today is barely economically viable and subsequently at risk of scale down or closure. Once production sites are decommissioned, their revival can take up to a decade or more to reach full operational capacity. The last remaining fully vertically integrated producers of antibiotic APIs at scale in the EU —maintain end-to-end

manufacturing capacity across Austria, Slovenia, Spain, Germany, Italy, Denmark and Hungary, with significant contributions from other EU member states.

Although they currently hold only a marginal share of the market, their combined installed capacity could meet the EU's entire demand and serve substantial shares of partner markets in the African Union and the United States for three essential antibiotic agents: the broad-spectrum amoxicillin, and the two critical second-line antibiotics vancomycin and ciprofloxacin. Additional capacity for the manufacturing of antibiotic APIs for a range of other antibiotics listed on both the EU's Critical Medicines List and the WHO's Essential Medicines List may reside in the EU's existing network of CDMOs, whose clients are facing similar challenges.

INITIATIVE

We aim to substantially increase Europe's share of global antibiotic API production through fully vertically integrated API manufacturing, strengthening our strategic autonomy up to fully autonomous capacity within the EU and safeguarding our public healthcare systems, as well as those in the African Union.

We believe it is of utmost political importance to support European fully vertically integrated antibiotic API manufacturers by creating an economically viable commercial framework for them to operate within, reduce the dependency of our pharmaceutical supply chains on the import of API, and in this way protect strategic assets and protect our healthcare systems from fluctuations of global trade. Europe must act now to safeguard its antibiotic supply, as well as the safe supply to its partners in Africa, and beyond. To secure and expand the production of antibiotic agents in Europe, the EU and its member states must commit to supporting fully vertically integrated manufacturing of antibiotic APIs in the EU.

We call on national and EU institutions, industry, and civil society to join forces in support of this initiative and herewith pass this Communiqué to the EU Member States and the European Union's *Health Emergency Preparedness and Response Authority's (HERA)* for further pursual.